IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

POZEN INC. Plaintiff, v. PAR PHARMACEUTICAL, INC. Defendant.	CIVIL ACTION NO. 6:08-cv-437-LED PATENT CASE
POZEN INC. Plaintiff, v. ALPHAPHARM PTY LTD. Defendant.	CIVIL ACTION NO. 6:09-cv-003-LED CONSOLIDATED WITH CIVIL ACTION NO. 6:08-cv-437-LED AND CIVIL ACTION NO. 6:09-cv-182-LED PATENT CASE
POZEN INC. Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. Defendant.	CIVIL ACTION NO. 6:09-cv-182-LED CONSOLIDATED WITH CIVIL ACTION NO. 6:08-cv-437-LED AND CIVIL ACTION NO. 6:09-cv-003-LED PATENT CASE
POZEN INC. Plaintiff, v. DR. REDDY'S LABORATORIES, INC. Defendant.	CIVIL ACTION NO. 6:08-cv-437-LED PATENT CASE

POZEN INC.'S AMENDED COMPLAINT

Plaintiff Pozen Inc. ("Pozen") complains against Par Pharmaceutical, Inc. ("Par"), Alphapharm Pty Ltd. ("Alphapharm"), Teva Pharmaceuticals USA, Inc. ("Teva") and Dr. Reddy's Laboratories, Inc. ("DRL"), and alleges the following:

The Parties

1. Pozen is a Delaware corporation, having its principal place of business at 1414 Raleigh Road, Chapel Hill, North Carolina 27517. Pozen is a specialty pharmaceutical company dedicated to developing therapeutic advancements for diseases with unmet medical needs. Pozen currently specializes in innovative drug products designed to alleviate patient pain and suffering.

2. On information and belief, Par is a New Jersey corporation with its principal place of business at 1 Ram Ridge Road, Spring Valley, New York 10977.

3. On information and belief, Par is in the business of developing, manufacturing, distributing and selling generic drug products through the United States, including for distribution and sale in this district.

4. On information and belief, Alphapharm is an Australian corporation with its principal place of business at Chase Building 2, Wentworth Park Road, Glebe, NSW Australia 2037.

5. On information and belief, Alphapharm is in the business of developing, manufacturing, distributing and selling generic drug products throughout the United States, including for distribution and sale in this district.

6. On information and belief, Teva is a Delaware corporation with its principal place of business at 1090 Horsham Road, P.O. Box 1090, North Wales, Pennsylvania 19454-1090.

7. On information and belief, Teva is in the business of developing, manufacturing, distributing and selling generic drug products throughout the United States, including for distribution and sale in this district.

8. On information and belief, DRL is a New Jersey corporation with its principal place of business at 200 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807-2862.

9. On information and belief, DRL is in the business of developing, manufacturing, distributing and selling generic drug products throughout the United States, including for distribution and sale in this district.

Nature of the Case

10. This is an action for infringement of United States Patent Nos. 6,060,499 (a true and correct copy is attached hereto as Exhibit A), 6,586,458 (a true and correct copy is attached hereto as Exhibit B) and 7,332,183 (a true and correct copy is attached hereto as Exhibit C). This action is based on the Patent Laws of the United States as found in 35 U.S.C. § 100, *et seq*.

Jurisdiction and Venue

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(c), (d) and 1400(b).

12. This Court has personal jurisdiction over Par because Par has systematic and continuous contacts with this jurisdiction.

13. On information and belief, Par manufactures, sells and distributes pharmaceutical products throughout the United States and in this judicial district.

14. This Court has personal jurisdiction over Alphapharm because Alphapharm has systematic and continuous contacts with this jurisdiction.

15. For example, Alphapharm places into the stream of commerce in this district generic galantamine product, which is offered for sale at Wal-Mart store number 398 in Longview, Texas. On information and belief, this and other products are sold and distributed by Alphapharm in this district through retail pharmacies, such as Wal-Mart and Walgreens.

16. This Court has personal jurisdiction over Teva because Teva has systematic and continuous contacts with this jurisdiction.

17. On information and belief, Teva manufactures, sells and distributes generic drug products throughout the United States, including for distribution and sale in this district.

18. This Court has personal jurisdiction over DRL because DRL has systematic and continuous contacts with this jurisdiction.

19. On information and belief, DRL manufactures, sells and distributes generic drug products throughout the United States, including for distribution and sale in this district.

Background

20. On May 9, 2000, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 6,060,499 ("the '499 patent"), entitled "Anti-Migraine Methods and Compositions Using 5-HT Agonists with Long-Acting NSAIDS." The '499 patent issued to Pozen as the assignee and is currently assigned to Pozen.

21. On July 1, 2003, the PTO issued U.S. Patent No. 6,586,458 ("the '458 patent"), entitled "Methods of Treating Headaches Using 5-HT Agonists in Combination with Long-Acting NSAIDS." The '458 patent issued to Pozen as the assignee and is currently assigned to Pozen.

22. On February 19, 2008, the PTO issued U.S. Patent No. 7,332,183 ("the '183 patent"), entitled "Multilayer Dosage Forms Containing NSAIDS and Triptans." The '183 patent issued to Pozen as the assignee and is currently assigned to Pozen.

23. On April 15, 2008, the United States Food and Drug Administration ("FDA") approved Pozen's New Drug Application ("NDA") for Treximet™, NDA No. 21-926. Treximet™ is a tablet for oral administration and contains 85 mg of sumatriptan (present as a succinate) and 500 mg of naproxen sodium.

24. Treximet™ is approved for the acute treatment of migraine attacks with or without aura.

25. Pursuant to 21 U.S.C. § 355(b), Pozen submitted patent information for the '499, '458 and '183 patents for inclusion in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book." The FDA thereafter listed the '499, '458 and '183 patents in the Orange Book in connection with the Treximet™ NDA.

Infringement by Par

26. On information and belief, Par filed papers with the FDA allegedly constituting an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of a generic version of Treximet™. On information and belief, the FDA assigned Par's ANDA submission ANDA No. 90-753 (hereinafter "Par's ANDA").

27. On information and belief, the product that is the subject of Par's ANDA is a tablet for oral administration that contains 85 mg sumatriptan (present as a succinate) and 500 mg naproxen sodium (hereinafter the "Par Generic Product").

28. On information and belief, Par intends that its Generic Product be used by consumers for the acute treatment of migraine attacks with or without aura.

29. On October 8, 2008, Par sent a letter to Pozen (the "Par Notice Letter") advising that Par had submitted ANDA No. 90-753 and that Par's ANDA contained certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as Paragraph IV Certifications, that in Par's opinion, the '499, '458 and '183 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, sale or importation of the product that is the subject of Par's ANDA.

30. The Par Notice Letter also advised that Par intends to market its Generic Product before the expiration of the '499, '458 and '183 patents.

31. The Par Notice Letter also included an Offer of Confidential Access to Par's ANDA. Pozen requested access to Par's ANDA, and thereafter Par provided to Pozen what appeared to be at least a portion of Par's ANDA.

32. Pozen sued Par on November 14, 2008 for infringement of the '499, '458 and '183 patents.

Infringement by Alphapharm

33. On information and belief, Alphapharm filed papers with the FDA allegedly constituting an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of a generic version of Treximet™. On information and belief,

the FDA assigned Alphapharm's ANDA submission ANDA No. 90-872 (hereinafter "Alphapharm's ANDA").

34. On information and belief, the product that is the subject of Alphapharm's ANDA is a tablet for oral administration that contains 85 mg sumatriptan (present as a succinate) and 500 mg naproxen sodium (hereinafter the "Alphapharm Generic Product").

35. On information and belief, Alphapharm intends that its Generic Product be used by consumers for the acute treatment of migraine attacks with or without aura.

36. On November 21, 2008, Pozen received a letter from Alphapharm (the "Alphapharm Notice Letter") advising that Alphapharm had submitted ANDA No. 90-872 and that Alphapharm's ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as Paragraph IV Certifications, that in Alphapharm's opinion, the '499, '458 and '183 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale or importation of the product that is the subject of Alphapharm's ANDA.

37. The Alphapharm Notice Letter also advised that Alphapharm intends to market its Generic Product before the expiration of the '499, '458 and '183 patents.

38. The Alphapharm Notice Letter also included an Offer of Confidential Access to Alphapharm's ANDA. Counsel for Pozen requested access to Alphapharm's ANDA, and thereafter Alphapharm provided to Pozen what appeared to be at least a portion of Alphapharm's ANDA.

39. Pozen sued Alphapharm on January 2, 2009 for infringement of the '499 and '458 patents. On January 29, 2009, Pozen amended its complaint against Alphapharm to include infringement of the '183 patent.

Infringement by Teva

40. On information and belief, Teva filed papers with the FDA allegedly constituting an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of a generic version of Treximet™. On information and belief, the FDA assigned Teva's ANDA submission ANDA No. 91-146 (hereinafter "Teva's ANDA").

41. On information and belief, the product that is the subject of Teva's ANDA is a tablet for oral administration that contains 85 mg sumatriptan (present as a succinate) and 500 mg naproxen sodium (hereinafter the "Teva Generic Product").

42. On information and belief, Teva intends that its Generic Product be used by consumers for the acute treatment of migraine attacks with or without aura.

43. On April 15, 2009, Pozen received a letter from Teva's Senior Director of Regulatory Affairs (the "Notice Letter") advising that Teva had submitted ANDA No. 91-146 which seeks approval to "engage in the commercial manufacture, use, or sale of Sumatriptan and Naproxen Sodium Tablets, Eq. 85 mg base/500 mg . . .." The Notice Letter further advises that Teva's ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as Paragraph IV Certifications, that in Teva's opinion, the '499, '458 and '183 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale or importation of the product that is the subject of Teva's ANDA.

44. The Teva Notice Letter also advised that Teva intends to market its Generic Product before the expiration of the '499, '458 and '183 patents.

45. Pozen sued Teva on April 24, 2009 for infringement of the ’499 and ’458 patents. On July 6, 2009, Pozen amended its complaint against Teva to include infringement of the ’183 patent.

Infringement by DRL

46. On information and belief, DRL filed papers with the FDA allegedly constituting an ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and sale of a generic version of Treximet™. On information and belief, the FDA assigned DRL’s ANDA submission ANDA No. 90-930 (hereinafter “DRL’s ANDA”).

47. On information and belief, the product that is the subject of DRL’s ANDA is a tablet for oral administration that contains 85 mg sumatriptan (present as a succinate) and 500 mg naproxen sodium (hereinafter the “DRL Generic Product”).

48. On information and belief, DRL intends that its Generic Product be used by consumers for the acute treatment of migraine attacks with or without aura.

49. On July 31, 2009, Pozen received a letter from DRL’s Vice President of Intellectual Property (the “DRL Notice Letter”) advising that DRL had submitted ANDA No. 90-930 and that DRL’s ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), commonly referred to as Paragraph IV Certifications, that in DRL’s opinion, the ’499, ’458 and ’183 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale or importation of the product that is the subject of DRL’s ANDA.

50. The DRL Notice Letter also advised that DRL intends to market its Generic Product before the expiration of the ’499, ’458 and ’183 patents.

51. The DRL Notice Letter also included an Offer of Confidential Access to DRL's ANDA. Counsel for Pozen requested access to DRL's ANDA, and thereafter DRL provided to Pozen what appeared to be at least a portion of DRL's ANDA.

Count I – Infringement of the '499 Patent

52. Pozen incorporates by reference and repeats the allegations in paragraphs 1-51 above.

53. Par's submission of ANDA No. 90-753 to the FDA, including the Paragraph IV Certification to the '499 patent contained therein, constitutes infringement of at least claims 9, 15, 17 and 18 of the '499 patent under 35 U.S.C. § 271(e)(2)(A).

54. Par's commercial manufacture, offer for sale, sale, importation or use of the Par Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 9, 15, 17 and 18 of the '499 patent.

55. Upon information and belief, Par was aware of the '499 patent when it submitted its ANDA.

56. Alphapharm's submission of ANDA No. 90-872 to the FDA, including the Paragraph IV Certification to the '499 patent contained therein, constitutes infringement of at least claims 9, 15, 17 and 18 of the '499 patent under 35 U.S.C. § 271(e)(2)(A).

57. Alphapharm's commercial manufacture, offer for sale, sale, importation or use of the Alphapharm Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 9, 15, 17 and 18 of the '499 patent.

58. Upon information and belief, Alphapharm was aware of the '499 patent when it submitted its ANDA.

59. Teva's submission of ANDA No. 91-146 to the FDA, including the Paragraph IV Certification to the '499 patent contained therein, constitutes infringement of at least claims 9, 15, 17 and 18 of the '499 patent under 35 U.S.C. § 271(e)(2)(A).

60. Teva's commercial manufacture, offer for sale, sale, importation or use of the Teva Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 9, 15, 17 and 18 of the '499 patent.

61. Upon information and belief, Teva was aware of the '499 patent when it submitted its ANDA.

62. DRL's submission of ANDA No. 90-930 to the FDA, including the Paragraph IV Certification to the '499 patent contained therein, constitutes infringement of at least claims 9, 15, 17 and 18 of the '499 patent under 35 U.S.C. § 271(e)(2)(A).

63. DRL's commercial manufacture, offer for sale, sale, importation or use of the DRL Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 9, 15, 17 and 18 of the '499 patent.

64. Upon information and belief, DRL was aware of the '499 patent when it submitted its ANDA.

Count II – Infringement of the '458 Patent

65. Pozen incorporates by reference and repeats the allegations in paragraphs 1-64 above.

66. Par's submission of ANDA No. 90-753 to the FDA, including the Paragraph IV Certification to the '458 patent contained therein, constitutes infringement of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

67. Par's commercial manufacture, offer for sale, sale, importation or use of the Par Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent.

68. Upon information and belief, Par was aware of the '458 patent when it submitted its ANDA.

69. Alphapharm's submission of ANDA No. 90-872 to the FDA, including the Paragraph IV Certification to the '458 patent contained therein, constitutes infringement of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

70. Alphapharm's commercial manufacture, offer for sale, sale, importation or use of the Alphapharm Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent.

71. Upon information and belief, Alphapharm was aware of the '458 patent when it submitted its ANDA.

72. Teva's submission of ANDA No. 91-146 to the FDA, including the Paragraph IV Certification to the '458 patent contained therein, constitutes infringement of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

73. Teva's commercial manufacture, offer for sale, sale, importation or use of the Teva Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent.

74. Upon information and belief, Teva was aware of the '458 patent when it submitted its ANDA.

75. DRL's submission of ANDA No. 90-930 to the FDA, including the Paragraph IV Certification to the '458 patent contained therein, constitutes infringement of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent under 35 U.S.C. § 271(e)(2)(A).

76. DRL's commercial manufacture, offer for sale, sale, importation or use of the DRL Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of at least claims 1-8, 10-12, 14, 15 and 22-32 of the '458 patent.

77. Upon information and belief, DRL was aware of the '458 patent when it submitted its ANDA.

Count III – Infringement of the '183 Patent

78. Pozen incorporates by reference and repeats the allegations in paragraphs 1-77 above.

79. Par's submission of ANDA No. 90-753 to the FDA, including the Paragraph IV Certification to the '183 patent contained therein, constitutes infringement of claims 1-5, 10-14 and 17-20 of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

80. Par's commercial manufacture, offer for sale, sale, importation or use of the Par Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of claims 1-5, 10-14 and 17-20 of the '183 patent.

81. Upon information and belief, Par was aware of the '183 patent when it submitted its ANDA.

82. Alphapharm's submission of ANDA No. 90-872 to the FDA, including the Paragraph IV Certification to the '183 patent contained therein, constitutes infringement of claims 1-5, 10-14 and 17-20 of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

83. Alphapharm's commercial manufacture, offer for sale, sale, importation or use of the Alphapharm Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of claims 1-5, 10-14 and 17-20 of the '183 patent.

84. Upon information and belief, Alphapharm was aware of the '183 patent when it submitted its ANDA.

85. Teva's submission of ANDA No. 91-146 to the FDA, including the Paragraph IV Certification to the '183 patent contained therein, constitutes infringement of claims 1-5, 10-14 and 17-20 of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

86. Teva's commercial manufacture, offer for sale, sale, importation or use of the Teva Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of claims 1-5, 10-14 and 17-20 of the '183 patent.

87. Upon information and belief, Teva was aware of the '183 patent when it submitted its ANDA.

88. DRL's submission of ANDA No. 90-930 to the FDA, including the Paragraph IV Certification to the '183 patent contained therein, constitutes infringement of claims 1-5, 10-14 and 17-20 of the '183 patent under 35 U.S.C. § 271(e)(2)(A).

89. DRL's commercial manufacture, offer for sale, sale, importation or use of the DRL Generic Product would infringe and/or induce infringement, either literally or under the doctrine of equivalents, of claims 1-5, 10-14 and 17-20 of the '183 patent.

90. Upon information and belief, DRL was aware of the '183 patent when it submitted its ANDA.

Prayer for Relief

In view of the foregoing, Pozen respectfully requests the following relief:

A. A judgment that the submission of Par's ANDA constitutes infringement of one or more claims of the '499, '458 and '183 patents;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Par's ANDA shall not be earlier than the expiration date of the '499, '458 and '183 patents, including any extensions thereof;

C. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Par, its affiliates, officers, agents, servants, employees and any person in active concert or participation with Par or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States of the Par Generic Product prior to the expiration of the '499, '458 and '183 patents, including any extensions thereof;

D. A judgment that the submission of Alphapharm's ANDA constitutes infringement of one or more claims of the '499, '458 and '183 patents;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Alphapharm's ANDA shall not be earlier than the expiration date of the '499, '458 and '183 patents, including any extensions thereof;

F. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Alphapharm, its affiliates, officers, agents, servants, employees and any person in active concert or participation with Alphapharm or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States of the Alphapharm Generic Product prior to the expiration of the '499, '458 and '183 patents, including any extensions thereof;

G. A judgment that the submission of Teva's ANDA constitutes infringement of one or more claims of the '499, '458 and '183 patents;

H. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Teva's ANDA shall not be earlier than the expiration date of the '499, '458 and '183 patents, including any extensions thereof;

I. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining Teva, its affiliates, officers, agents, servants, employees and any person in active concert or participation with Teva or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States of the Teva Generic Product prior to the expiration of the '499, '458 and '183 patents, including any extensions thereof;

J. A judgment that the submission of DRL's ANDA constitutes infringement of one or more claims of the '499, '458 and '183 patents;

K. An order pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of DRL's ANDA shall not be earlier than the expiration date of the '499, '458 and '183 patents, including any extensions thereof;

L. A permanent injunction under 35 U.S.C. § 271(e)(4)(B) restraining DRL, its affiliates, officers, agents, servants, employees and any person in active concert or participation with DRL or any of the foregoing, from the commercial manufacture, use, import, offer to sell or sale within the United States of the DRL Generic Product prior to the expiration of the '499, '458 and '183 patents, including any extensions thereof;

M. Costs and expenses incurred in pursuing this action; and

N. Any other relief the Court deems just and proper.

Respectfully submitted,

Dated: August 21, 2009

By: /s/ Stephen M. Hash

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CERTIFICATE OF SERVICE

The undersigned certifies that the foregoing document was filed electronically in compliance with Local Rule CV-5(a). As such, this motion was served on all counsel who are deemed to have consented to electronic service. Local Rule CV-5(a)(3)(A). Pursuant to Fed. R. Civ. P. 5(d) and Local Rule CV-5(d) and (e), all other counsel of record not deemed to have consented to electronic service were served with a true and correct copy of the foregoing by mail, email and/or fax, on this the 21st day of August, 2009.

/s/ Stephen M. Hash